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(71) [Applicant]
[Name or Appellation] Nippon Zeon Co., Ltd
[Address or Residence] 1-6-2
Marunouchi, Chiyoda-ku, Tokyo
(72) [Inventor]
[Full Name] Takashi Kawabat[Address or Residence] 6-7-1, Midori-cho, Hasuda-shi, SAITAMA(72)
[Inventor]
[Full Name] Shinichi Miyata
[Address or Residence] 40-1-1-138, Ooya, Ebina-shi, Kanagawa
(72) [Inventor]
[Full Name] Kiyoshi Takagi [Address or Residence] 25-7, Katabuki, Yokohama-shi, Kanazawa-ku,
Kanagawa
(74) [Agent]
[Patent Agent]
[Full Name] Hiroshi Ousaka

I.Title of The Invention: Shape Memory Alloy for Medical Use and Catheter

II. Scope of Claim for Patent

1. A shape memory alloy member for medical use which allows to vary a deformation starting condition of a shape memory alloy material member so that the middle part of longitudinal direction expands first at least.

2. A catheter characterized by varying deformation starting condition of the above shape memory alloy member so that the middle part of longitudinal direction expands first at least in the catheter which is mounted with a coil shaped shape memory alloy member.

III Detailed Description of The Invention

A.[Industrial applicability] This invention relates to a shape memory alloy member for medical use and a catheter and more specifically one for use to permanently dilate the stenosis of a tubular organ such as blood vessel.

B.[Prior Art] For treatment of angina pectoris or cardiac infarction, the so-called PTCA (Percutaneous Transluminal Coronary Angioplasty) catheter has hitherto been inserted, for example, into the stenosis of coronary artery of patient depending on cases. Namely, for treatment of a disease caused by stenosis of the coronary artery, besides the chemical treatment making use of a thrombolytic agent or the like, a surgical treatment is available to expand the stenosis with the PTCA catheter.

This kind of catheter has a plastic or a rubber balloon at the leading end thereof. After the catheter is inserted into the blood vessel to reach the stenosis thereof, the balloon is inflated to expand against the

vessel wall of stenosis. The catheter is then withdrawn. Though rather easy to perform, the above surgical treatment has a disadvantage that the effect of the treatment is not permanent, so the restenosis rate is high.

As an approach to improve the above defect, a system is proposed which dilates a blood vessel using a cylindrical shaped endoprosthesis made of a shape memory alloy in the blood vessel. For example, there are two patents, U.S. Pat. No. 3, 868, 956 and Japanese Patent Publication No. 61-6655. The former discloses a method wherein a shape memory alloy is worked as a endoprosthesis, its memory is by heating the wire memory of the original shape and deformed to a shape of a narrower diameter, which is fitted by use of a catheter into the stenosis of a blood vessel and then heated by use of electrical energy to restore the original shape and thereby dilate the blood vessel to expand the stenosis thereof. The latter patent discloses a method wherein a piece of shape memory alloy sheet, which is worked to a endoprosthesis of a diameter equivalent to the inner diameter of normal blood vessel without stenosis, annealed and deformed to a narrower diameter, is fitted into a desirable position of blood vessel with the use of a catheter and then heated by use of a laser beam or high frequency induction to restore the original shape thereof.

With the former approach, however, the cylindricalshaped deformed endoprosthesis of shape memory alloy is electrically heated by use of either an additional heater or the electrical resistance of the shape memory alloy itself, so there is a danger of current leak that might give an electric shock and yet it is necessary to use a complex system. Instead of an electrical current as used by the former approach, the latter approach uses laser beam or high frequency induction for heating, which will require an expensive complex system, though not mentioned in that invention.

C.[Background of The Invention] Consequently the applicant proposed a catheteras Pattent Application 62-97437, which realizes a means of dilation with which the operation is carried out easily and the surgical treatment is remarkably safe. The catheter is characterized in having a blocking member, such as a balloon, which prevents the flow of body fluid by operations conducyed outside of a human body arbitrarily, cylindrical shaped shape memory alloy fitted to the catheter, which resores the shape at a temperature above a transition point of the shape memory alloy, and a supplying means with which warming liquid is supplied to the outer surface of a catheter at the area of cylindrical member made of the above stated shape memory alloy. Namely, the desired shape is memorized beforehand, the cylindrical shaped shape memory alloy with a nallower diameter is heated by warming liquid, and the original shape is restored.

However, it was found that there is still a room for improvement in the above catheter related to the prior application after the inventor's further examinations although the invention brings excellent effects described above.FIG.

12 shows the state where a shape memory alloy coil is inserted to the stenosis of coronary artenary using a a catheter described in patent application No. S-62-9743 and the above stated stenosis is recovered the original shape by the coil's recovering action. (A) in the same Figure shows the state of the coil before recovering original shape and (B) in the same Figure shows the sate where the coil is recovering original shape.

A warming liquid 10 is sent into coronary arteries through a narrow hole 29 and an opening 29a made in a catheter 21 in order to expand the coil 28 made of shape memory alloy by heating the coil at the temperature above restoring temperature (transition temperature) and dilate stenosis 14 surrounded. The end regions of the coil 28a is expanded easily and restored to the original shape because they are fee ends. However, regions except the end regions 28a is not expanded easily compared to the end regions 28a and restoring original shape in the region delays because the regions are constrained by the end regions 28a. When the end regions 28a of the coil are thus brought in close contact to the inside wall of blood vessel, because the regions cannot move toward a central line, thus, the above constrain tends to be larger in the regions except the end regions. As a result restoring the original shape is prevented by the

stronger constrains above stated, and the coil 28 cannot reach to the stenosis, which doesn't allow the expantion of the area of stenosis.

D.[Object of Invention] It is an object of the invention to provide a shape memory alloy member and a catheter which uses the shape memory alloy member, which can be used for satisfactory treatment (particularly dilation) of the stenosis of a blood vessel or the like without any later restenosis.

E.[Constitution of The Invention] The first part of this invention relates to a coil shaped shape memory alloy member differing the transformation start condition of shape memory alloy member so that at least the middle region is expanded first among the end regions and the middle region.
In addition, the second part of this invention relates to a catheter which is caracterized by differing the transformation start condition of shape memory alloy member so that at least the middle region expands first among the end regions an the middle region in the catheter which mounts the coil shaped shape memory alloy member.

F [Description Of The Preferred Embodiments]
The following explains the embodiments of this invention.
FIG. 1 to FIG. 4 is an example of this invention.

In this case a PTCA catheter 1 comprises a main body 2 made of polyethylene, polyvinyl chloride, silicone rubber, polyurethane elastomer or the like and a balloon 3 made of elastic rubber attached to the tapering end of main body 2 and has a lumen 5 in the main body 2 along the length thereof to inject physiological saline 4, contrast medium or their mixture in the balloon 3 (or drain the same) . Along the axis of the main body 2, a throughhole lumen 7 to pass a guide wire 6 through is formed from end to end. A little behind the balloon 3, a shape memory alloy coil 8 made of a shape memory alloy for example, Ni-Ti alloy, is attached. Further, except for the part of main body 2 fitted with the balloon 3, almost the full length of the main body 2 is covered with a sheath 9, for example, made of polyurethane elastomer. The sheath 9 branches near the trailing end thereof to provide an inlet port 11 to inject warming liquid 10.

In the above setup, the coil 8 has such a property as to restore the original shape, namely, expand at a temperature above the transition point (transformation point Af) of the shape memory alloy. Being used in a living body, the coil 8 is preferably made of a shape memory alloy whose transition temperature is at least 3 degree in Celsius higher than the body temperature and particularly between 38 and 48 degree in Celsius. Such transition temperature can be achieved by selecting a proper composition of the shape memory alloy. From the inlet port 11 of sheath 9, warming liquid 10 is injected to flow through a space as defined by the inside surface of sheath 9 and outside surface of main body 2 to reach the coil 8. For the above heating liquid, a transfusion solution, physiological saline, contrast medium etc. may be used, which is warmed hot enough in full consideration of a fact that the temperature lowers as the solution flows out of the catheter and mixes with blood or body fluid but not so hot as to cause any heating damage of the inner wall in the blood vessel.

For the above coil 8, a wire of shape memory alloy is wound to a coil of a desired diameter, annealed and then rewound to a coil of a smaller diameter around the outside of the catheter. To avoid the coil from sliding from the given position, the corresponding part 2a of main body is narrowed to a smaller outer diameter. It is a matter of course that instead of narrowing that part the coil may be stopped with a retaining ring, for example, made of silicone rubber or the like.

A remarkable feature of this example is that the middle region 8b of the coil 8 has a transition point lower than at both end regions 8a thereof. A detailed description will be given about this point below.

Even a same composition of shape memory alloy may have a different transition point depending on the condition of annealing process for memorizing the original shape. FIG. 5 shows curves of annealing time

of Ni-Ti (50 atomic percent Ni) versus transition point Af, corresponding to heating temperatures of 400, 450 and 500 degree in Celsius, respectively.

To give the aforementioned distribution of transition point along the coil 8, a setup of FIG. 6 is used. A shape memory alloy wire 8 is wound around a cylindrical metal mold 15 at given pitches and put into a furnace core tube 16. In a stream of inert gas 18, the coil 8 is then heated by a heater 17A located around the middle region of coil 8. The middle region 8b of coil 8, which is closer to the heater 17A, is heated hottest and in both end regions 8a of coil 8 the farther from the heater 17A, the lower the heating temperature. A coil thus worked to the dimensions of metal mold 15 and annealed for memory of the original shape is wound around the given part of catheter having a smaller diameter to give a coil of the corresponding diameter. Alternatively, after the coil is annealed at a uniform temperature for memory of the original shape, both end regions of the coil may be coated with a thermal insulator material. Also when the latter type of coil is applied, the middle part of coil reaches the transition temperature earlier than the both end regions thereof.

The practical embodiment is explained as follows.

(1) For the former type, Ni-Ti alloy of 0.5 mm in diameter wire (50 atomic percent Ni) was wound around a metal mold to form a coil 5 mm in diameter, which was annealed 30 min using a setup of FIG. 6. For annealing, the middle region 8b was heated at 450 degree in Celsius, and both end regions 8a at 500 degree in Celsius. The wire of the coil was wound around the catheter to give a coil 2.5 mm in diameter.

(2) For the latter type, a Ni-Ti alloy wire wound around a metal mold by the same method as in the above example (1) was heated 30 min at a uniform temperature of 500 degree in Celsius. The coil was then coated with polyurethane solution as far as 1.5 mm from both ends. After drying, there was formed 0.05 mm thick polyurethane coating. The wire of the above coil was rewound to a coil of smaller diameter as in the above example (1).

The coils thus made were each immersed in running water of 45 degree in Celsius to determine how the original shape was restored with time. FIGs. 7 (A) and (B), referring to the above coil examples (1) and (2), respectively, give a rough idea about the restoration of the original shape with these examples.

It is seen from FIGs. 7 (A) and (B) that with both coil examples, the middle region 8b of the coil started recovery of the original shape in the running warm water earlier than the end regions 8a. In case of the coil example (1), the middle region 8b is annealed at higher temperatures than both end regions 8a, so the middle region 8b has lower transition points as compared to the both end regions 8a (see FIG. 5) . After the start of warm water passage, therefore, first, the middle region 8b reaches the transition points thereof to restore the original shape and both end regions 8a do so with a delay. In case of the coil example (2), because of polyurethane coating, both end regions 8a warm slower than the middle region 8b, so the regions 8a reach the transition point later than the region 8b.

As in FIG. 11, the catheter 1 of the above setup is inserted with the balloon fitted at the tapering end, for example, from a femoral artery 15 as far as the coronary artery 13 of the patient's heart 12 (it is noted that only a schematic sketch is given to ease the understanding) . The main catheter 2 is guided to the given position by the sheath 9, when the guide wire 6 as mentioned above is available for satisfactory control. The catheter, as it is guided, can be monitored by roentogenography of the catheter and shape memory alloy coil.

After the catheter is successfully inserted to a stenosis 14 of artery 13 as in FIG. 8 (A), physiological saline or the like 4 is injected to inflate the balloon 3 so the balloon 3 may come in close contact to the inner wall of blood vessel as in FIG. 8 (B) temporarily stopping the flow of blood and other body fluid there. It is noted that the main body 2 must be moved ahead beforehand by the control of guide wire 6 so far as the coil 8 is uncovered from the sheath 9 for exposure as in FIG. 8 (A) . In FIG. 8 (C), physiological saline 10 warmed, for example, to a constant temperature of 50 degree in Celsius. is injected from the inlet port 11 of the sheath 9. The warmed physiological saline 10 from the inlet port 11 flows, as indicated clearly in

FIG. 4, along a space formed inside the sheath 9 (and outside of the main body) to pour where the coil 8 is located. Physiological saline, as it comes out of the sheath and mixes with blood and other body fluid that remain there, becomes cooler at first but the temperature rises gradually until the coil 8 is warmed hotter than the transition temperature thereof to recover the original expanded shape as indicated in FIG. 8 (C) . Then the recovering the original expanded shape transits to the end regions gradually to expand the stenosis 14 and the adjacent area. (The state of completion of restoring in the coil 8 is shown as interrupted lines in the FIG. 4) . Then, the size of balloon 3 is deflated and reduced by discharging physiological saline and the catheter is withdrawn as in FIG. 8 (E) . Thus, the coil is placed in a blood vessel expanding the stenosis 14 to achieve the purpose of treatment.

With the catheter 1 of the above example, the stenosis of a blood vessel can be expanded permanently, as mentioned above, without any danger of restenosis. Further, since the warming liquid is not passed through inside of the main body but outside thereof and inside of the sheath, a larger lumen can be secured for the liquid flow, allowing use of a warming liquid of lower temperature. This means safer operation, faster liquid injection, and also that the main body itself can be made thinner (since the lumen for the passage of warming liquid is not necessary) . As a result, this kind of catheter is easy to insert into a fine vessel such as the coronary artery. Further, with use of the sheath, the catheter can be inserted easier and more reliably. Besides, since the coil 8 starts expanding first at the middle region and expanding extends toward both ends 8a, the coil can expand and recover the original shape thereof without any constraint. Thus, there is no concern of uncertain expantion, that was explained in Figure 12.

Different from the heating methods of prior art, the shape memory alloy coil 8 is heated with warmed physiological saline or transfusion solution which can be injected under full temperature control. Thus, the surgery is much safer. In addition, it is easy to prepare warming liquid of a given temperature. This means a reducing of surgery cost.

To endow the coil with a distribution of transition point as mentioned with the above coil example (1), the following methods are available besides the one as described above referring to FIG. 6.

In FIG. 9, a cylindrical shaped heater 17B is installed inside a furnace core tube 16. A Ni-Ti alloy wire coil (not shown) wound around a metal mold is inserted inside the heater 17B and a cooling line 19 (coiled pipe for cooling liquid circulation) is added around each end of the wire coil. Thus, individual regions of the wire coil can be annealed at different temperatures as with the coil example (1) to achieve the intended distribution of transition point along the length of coil.

In FIG. 10 a number of independent annular sheathed heaters 17C (1 mm in diameter) charged with carbon powder are aligned inside a furnace core tube 16. A Ni-Ti alloy wire coil 8 wound around a metal mold 15 is inserted inside these sheathed heaters 17C. By passing different currents through individual sheathed heaters 17C (a larger current at the middle region of the wire coil and a smaller current at both ends of the coil), individual regions of the wire coil are annealed at different temperatures as with the coil example (1) to achieve the intended distribution of transition point along the length of coil.

In the case of the coil of example (1), the shape memory alloy coil is endowed with a given distribution of transition point by using different temperature for annealing. It will however be understood from FIG. 5 that the coil can be endowed with such distribution of transition point by annealing individual regions of the coil at a uniform temperature but for different durations of time. For this purpose, in FIG. 9, cooling liquid can be passed through the cooling lines 19 for cooling the coil after a given time during annealing, or in FIG. 10, the independent heaters 17C can be individually switched off at proper timings.

On the other hand, a coil of the example (2) that is annealed to a uniform transition point along the whole length thereof and treated so as to reach the transition point earlier in the middle region thereof than in both end regions thereof for recovery of the original shape at nonuniform timing can be worked as follows. For example, the wire of given end regions of the coil is made thinner so these end regions may have a

smaller heat capacity. In the blood vessel, the shape memory alloy coil warms up to a temperature almost equivalent to the body temperature. Coming in contact to a slightly hotter warming water, both end regions of the coil which are made of thinner wire for smaller heat capacity warms as these regions absorb heat energy from the warming water. As a result, the warming water that has been cooled reabsorbs heat energy from the thinner wire regions of the coil to retard heating of such regions.

The above catheter can be percutaneously inserted from the femoral artery or other blood vessels, being particularly useful for the therapy of obstructive arteriosclerosis.

Although embodiments of the present invention have been described, it should be understood that various modifications can be made to the described embodiments without departing from the technical spirit of the invention.

For example, the above shape memory alloy may be variously changed in alloy type, composition and shape. Any alloy type that irreversibly recovers the original shape as in the above examples is applicable. Depending on applications, an alloy type capable of reversible transition (that shrinks when cooled) may also be used. The mounting position and/or working pattern of the shape memory alloy member need not be limited to the above description. It is noted that the catheter of the invention can be inserted not only in the stenosis of blood vessel but in other locations, for example, such part of blood vessel whose wall has become so thin as to be liable to damages.

G.[Advantageous Effect of The Invention] As mentioned above, since at least the end regions of the coil differ from the middle region thereof in the transformation start condition of shape memory alloy (for example, the transformation start temperature and/or timing), the shape memory alloy member can change the shape thereof in a more desirable mode. As a result, the shape memory alloy member can rewind the original shape along the whole length thereof with no such trouble that the recovery of the original shape at one region of coil may prevent or suppress the recovery of the original shape at any other region thereof. Accordingly, the affected part of a patient's body, for example, a blood vessel can reliably be treated. Further, if such shape memory alloy coil is retained at the treated part of a patient's body, recurrence of the trouble (for example, restenosis of blood vessel) can reliably be prevented there.

IV. [BRIEF DESCRIPTION OF THE DRAWINGS]

The drawings from FIG. 1 to FIG. 11 show the embodiment of the present invention.
FIG. 1 is a perspective view of a catheter of the invention.
FIG. 2 is a cross section of the main part of the catheter.
FIG. 3 is a perspective view of the sheath.
FIG. 4 is a cross section of the catheter showing the transition status of a shape memory alloy coil thereon.
FIG. 5 is a diagram showing the relation between the heat treatment condition and transition temperature of a shape memory alloy.
FIG. 6 is a schematic section of a heating furnace.
FIG. 7 (1) and FIG. 7 (2) are a diagram showing transition starting temperature in each part of a shape memory alloy.
FIGs. 8 (A), FIGs. 8 (B), FIGs. 8 (C), FIGs. 8 (D) and FIGs. 8 (E) are enlarged sections of a stenosis of blood vessel fitted with the catheter of the invention and correspond to successive steps of the patency of stenosis.
FIGs. 9 and 10 are schematic perspective inside views of other examples of the heating furnaces used for the invention.
FIG.11 is a schematic diagram of the catheter of the invention when it is inserted.
FIGs. 12 (A) and FIGs.12 (B) are enlarged sections of a shape memory alloy coil showing the transition status of a shape memory alloy coil inside the blood vessel using a conventional catheter.

The followings are the names for the symbols in the drawings.

1.....Catheter
2.....Catheter main body
3.....Balloon
4.....Physiological saline
6.....Guide wire
8.....Shape memory alloy coil
8a.....End region of shape memory alloy coil
8b.....Middle region of shape memory alloy coil
9.....Sheath
10.....Warming liquid
13.....Coronary artery vessel
14.....Stenosis

Agent: Hiroshi Ousaka (Patent Agent)